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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/261,068 03/02/99 MAHANT

V

HM22/1109

EXAMINER

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GABEL, G

ART UNIT	PAPER NUMBER
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1641

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DATE MAILED:

11/09/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/261,068	Applicant(s) Mahant et al.
Examiner Gailene R. Gabel	Group Art Unit 1641

Responsive to communication(s) filed on Sep 27, 1999

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- Claim(s) 1-21 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 1-21 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claims _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) _____.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

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DETAILED ACTION

Amendment Entry

1. Applicant amendment and response filed 9/27/99 is acknowledged and has been entered. Claims 1, 4, 6-7, 10, 12-17, and 21 have been amended. Claim 16 has been added. (Note: claim 16 has been noted as previously missing . Claim 16 reciting “measuring creatinine” finds support in page 10 of the specification. Currently, claims 1-21 are pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reason of record.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reason as follows.

Claim 1, as amended, is indefinite by failing to recite active, positive method steps by reciting “has/have substantial binding to the”, first and second occurrence. Active method steps

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such as --substantially binds the-- or equivalent language is suggested but not required. See also amended claim 12.

Claims 13-21 remain rejected under 35 USC § 112, fifth paragraph for reciting improper multiple dependent claims. Claims in the multiple dependent form shall contain a reference, **in the alternative only**, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. See page 4 of Paper No. 3.

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In this case, the specification does not appear to provide any literal support for the recitation of “wherein the vessel has at least two walls with one wall being more deformable than the other wall”. Recitation of claim limitation lacking literal support in the specification constitutes new matter.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doshi et al. (US 5,766,552) in view of Kelland et al. (US 4,663,029) for reasons of record.

Response to Arguments

5. Applicant argues that claims 13-21 are currently recited in the proper multiple dependent form by reciting “The method of any of claims 1-12...”.

In response, Examiner restates that in order to obviate the current 35 USC § 112 fifth paragraph rejection to claims 13-21, applicant must amend the multiple dependent claims so as to recite dependency, **in the alternative only**, to more than one claim previously set forth.

6. Applicant argues that Doshi et al. fail to teach use of magnetic force for separation of blood cells from a blood cell containing fluid and further argues that Doshi et al. utilize a filter rather than a magnetic force; thereby, teaching away from use of magnetic form. Applicant also argues that Kelland et al. fail to teach production of cell-containing network and separation thereof; Kelland, instead, disclose separation of individual particles from a slurry; thereby,

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teaching away from cell-containing network separation. Applicant further argues that there is no teaching, suggestion, nor provision of a motivation to combine both references (*supra*) in order to arrive at the teaching of the instant invention.

In response, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Doshi et al. disclose a method for separating red blood cells from whole blood or a fraction thereof, by agglutinating or aggregating whole blood with a mixture of antibodies and antibody coated particles to form a cell-containing network (clusters / aggregates) comprising red blood cells. The combination of free agglutinating agents and nucleating particles coated with agglutinating agents provides for rapid and complete formation of cell-containing network (agglutination) of red blood cells. Doshi et al. disclose that the porous iron oxide particles used in the agglutination process are **magnetizable** polyacrolein beads. Indeed, Doshi et al. teach combining cells, additives, and particles in order to form a conglomeration of selected cellular network.

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On the other hand, Kelland et al. disclose selective separation of particles according to **particle magnetic susceptibility, independent of density, size, and shape of the particles.** A magnetic field is provided in the separation region which is oriented transversely to the longitudinal axes of parallel rods. Kelland et al. teach that the method is capable of handling high concentration slurry, eg. whole blood with red and white blood cells. In stating that his method has the capacity to separate particles, and that separation process is independent of properties aforementioned, Kelland inherently teaches that his method can be utilized to separate larger elements, i.e. aggregates, cellular networks, etc. and direct them into a separate flow path.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the separator and method of magnetic separation as taught by Kelland et al. with the teachings of Doshi et al. in agglutinating or aggregating red blood cells prior to separation because Doshi et al. specifically teach the use of magnetizable polyacrolein beads for use in formation of cell-containing networks (complete agglutination or formation of RBC clusters) and Kelland specifically teach applying his method in separation of cells attached to magnetic particles or beads, resulting in the formation of cell-containing networks, as those taught by Doshi et al. Furthermore, Kelland specifically teach the capacity of his method to separate particles according to **magnetic susceptibility, independent of density, size, and shape,** such as the agglutinated cells in the method of Doshi et al. formed into a cell-containing network. One of ordinary skill in the art would have been motivated to complement the method of Doshi et al. in cellular separation using Kelland-type separator and technique because of the

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heightened level of selectivity achievable in separation of complex particle systems in incorporating the use of magnetic force as taught by Kelland et al.

7. Applicant's arguments filed have been fully considered but are not deemed persuasive.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Gailene R. Gabel 11/4/99

Gailene R. Gabel
Patent Examiner
Art Unit 1641

James C. Housel 11/8/99
JAMES C. HOUSEL
SUPERVISORY PATENT EXAMINER